NNFA National Nutritional Foods Association

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Registration of Food Facilities Under the Public Health Security and bioterrorism Preparedness and Response Act of 2002; **Docket No. 02N-0276**

Dear Sir/Madam,

The National Nutritional Foods Association (NNFA) is the largest and oldest trade association representing the natural products industry. Our members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics. These are NNFA's comments on the Food and Drug Administration's (FDA) proposed rule on "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

NNFA recognizes that implementing section 305 (Registration) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act) presents a daunting, but extremely worthwhile task. Our primary concerns, then, are to ensure that the scope of the retail exemption is clear and unambiguous and that registration is as simple and straightforward as possible.

1. The Retail Exemption

FDA should list health food stores as retail facilities

FDA proposes to exempt "retail facilities" from the registration requirement for food facilities under the Act. Under proposed section 1.2279(c)(11), a "retail facility" is a facility that sells food products directly to consumers only. FDA states that a retail facility includes, but is not limited to, grocery and convenience stores, vending machine

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locations, and commissaries. FDA should expand on this list of exempt retail facilities by stating in the final rule that the term includes health food stores.

> *NNFA agrees with FDA that the term "retail facility" includes facilities that "manufacture/process food in that facility solely for direct sale to consumers from that same facility."*

NNFA appreciates FDA's recognition that the definition of "retail facility" in Section 1.227(c)(11) includes facilities "that manufacture/process food in that facility solely for direct sale to consumers from that same facility." Retail facilities that operate a juice – bar, repackage nuts or dried fruits that are received in bulk, or that unpack and display produce are good examples of some of the manufacturing/processing activities that take place in a retail setting. As expressed in our earlier comments, we believe that Congress did not intend for retail food preparation, or processing, to be a trigger for the registration requirement. In fact, restaurants are specifically listed in the Act as exempt facilities. NNFA very strongly urges FDA to retain this point of clarification in the final rule.

> *NNFA urges FDA to clarify the distinction between retail facilities and mixed facilities, and to elaborate on what it considers "incidental activities"*

FDA should identify in the final rule exactly when the line between "retail facility" and "mixed facility" is breached and when an activity exceeds the "incidental" level so that retailers know when registration is required. Furthermore, FDA should not draw this line so that retailers are unnecessarily subject to registration as a consequence of activities likely to occur in the usual course of operating a retail food establishment.

FDA states a "mixed-type facility" is one that "performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a retail facility. In order to determine whether a mixed-type facility must register, FDA will consider whether the activity that would require registration is merely incidental to the activities of an exempt facility. If activities are merely incidental, the facility need not register." *68 Fed. Reg. 22, 5381*

NNFA would appreciate clear guidance as to when a retail establishment becomes a "mixed facility." FDA should also provide guidance for what it considers incidental activities. Examples would be useful. For instance, would providing deli trays to a local business or catering company be a direct to consumer sale? What if this was a routine sale? How about selling ingredients, or even that same deli tray, for use at a bake sale? Or donating "day old" bakery items for distribution at a local senior center or to a homeless group? Is transportation by the retailer to the off-site location a determining factor? What is the status of an in-store bakery that produces goods that are also sold in another store under the same ownership? What about a retailer that occasionally, or more than occasionally, fulfills a mail-order of 25 bottles of vitamin C to one customer?

NNFA argues that FDA should provide some latitude for activities, like those described above, that occur in the usual course of operating a retail food establishment. The conference report on the Act provided that the term "retail food establishment" includes establishments that store, prepare, package, serve or otherwise provide articles of food directly to the retail consumer for human consumption. The report then states that this term does not include a warehouse that does not provide articles of food directly to a retail consumer as its primary function. Legislative history on the Act also provides that "retail food establishments" are exempt from registration and this includes "facilities attendant to their operations, which are under the same ownership or management." *148 Cong. Rec at H2726 and H2858.* In both instances, Congress offers companies, once they are identified as "retail food establishments," some latitude to do business without unnecessary restrictions.

Retailers should not be placed in the unworkable position of routinely having to determine the final destination of the food products they sell. Nor should they be required to register because of the incidental sale of bulk quantities. Somewhere short of availing themselves to wholesaling or distribution opportunities, retailers should be granted latitude in this area when "direct sale to consumers" is their primary function.

Retail sale of food for animal consumption should not trigger the registration requirement

FDA asked for comments on whether the retail exemption should be applied to food for animal consumption. Numerous retail groceries, including health food stores, offer pet food for sale. NNFA strongly argues that the retail exemption should be applied to food for animal consumption in the same way it applies to food for human consumption. To do otherwise is illogical, would virtually eliminate the benefit of a retail exemption for a majority of retailers, and in effect, provide a more stringent requirement for food sold to companion animals than for their owners.

Retail co-ops should not be required to register.

In the discussion section relevant to proposed section 1.227(d), the definition of farm, FDA states that "FDA is proposing to require co-op facilities that manufacture/process, pack, or hold food, and that are not subject to the farm exemption, to register with FDA. Co-ops are organizations formed to perform activities, including manufacturing/processing or packing food, for their members. The product of these activities is distributed to the members of the public."

FDA may not be aware of the numerous retail co-ops that exist and that, aside from cooperative ownership, operate no differently than any other retail establishment. These establishments should be exempt from registration just as other retail establishments are, however the discussion section regarding 1.227(d) potentially makes their status unclear. NNFA suggests that FDA make it clear that "co-op facilities that manufacture/process,

pack, or hold food, and that are not subject to the farm or retail exemption" must register with FDA.

II. Food Product Categories

FDA should retain, but modify, the food category selections under Dietary Supplements in the Food Facility Registration Form.

NNFA appreciates the value of collecting information relative to the general product categories; however we are concerned that some dietary supplement products may not fit neatly into the categories that are proposed and this will create confusion for companies trying to accurately fill out the Food Facility Registration Form. For instance, CoQ10 or beta-glucan supplements do not fit into any of the categories provided.

NNFA urges FDA to include another "optional selection" category of "other" under Dietary Supplements on the registration form. Both the Federal Food Drug and Cosmetic Act (FFD&C Act) definition of dietary supplement and the variety of dietary supplements on the market are larger than the selections offered. This necessitates an "other" category under Dietary Supplements in order to insure the accuracy of the information FDA collects.

NNFA also urges FDA to eliminate the references to 21 CFR 170.3 underneath any category that is specific to dietary supplements. This would convert all of the subcategories under "12. DIETARY SUPPLEMENTS" to "optional selections." 21 CFR 170.3 provides definitions strictly in the context of food additive regulations. Dietary supplements are excluded from the definition of a food additive in section 201(s)(6) of the FFD&C Act. Referencing 21 CFR 170.3 in the context of dietary supplements will lead to confusion, has created problems in the past, and FDA should therefore modify the Food Facility Registration form accordingly.

III. Availability of Food Registration Information

FDA should provide public disclosure of the fact of registration by a company and provide a mechanism to ensure companies themselves have access to registration information that has been filed with FDA

Information gathered in the context of registration is not subject to public disclosure under the Freedom of Information Act (FOIA). However, NNFA is concerned that companies may need a way to verify that a supplier or distributor is registered with FDA. Public disclosure of the *fact* of registration would therefore be useful.

It would also be useful for FDA to develop a way, apart from using the FOIA procedure and publish it in the rule, for companies to request a copy from FDA of their current registration form should they need a reference copy. FDA should also consider sending a

copy of the most current form they have on record to each registered company, perhaps electronically, on a yearly basis in order to remind them to update their registration form if necessary. This could also provide for a useful test of the system.

In conclusion, NNFA will make every effort to convey the requirements of the final rule to the natural products industry at large. Please contact me if you have any questions about these comments, or otherwise, at (800) 966-6632, ext. 232.

Sincerely,

David Seckman
CEO/Executive Director